Results were similar in the ITT population (HER2+ or HER2- patients). CONCLUSIONS: Utility values for patients with HER2+ MBC are generally similar for patients receiving letrozole plus lapatinib or letrozole plus placebo. Post-progression utility values were based largely on a single assessment for each patient and are may not be representative of patient utility during all post-progression survival.

PCN106

IMPACT OF AN INDIVIDUAL'S LOCUS OF CONTROL ON UTILITY VALUES FOR HEAD AND NECK CANCER HEALTH STATES

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OBJECTIVES: The determinants of utilities for health are largely unknown. The psychosocial construct *Locus of control* (LOC) describes the extent to which individuals feel their health is determined by their actions, by a powerful external figure, or by chance. LOC is associated with health-related quality of life among cancer patients but its impact on utilities has not been examined. The objective was to estimate the effect of LOC on utilities for head and neck cancer (HNC) health states among Canadians without cancer. **METHODS:** A convenience sample of respondents without cancer was recruited according to the age- and sex-distribution of Canada in Vancouver and Toronto. Standard gamble utilities were elicited for health states describing HNC stage and type. Standardized health state descriptions were based on literature review, trial data, and feedback from clinicians experienced in HNC treatment and quality-of-life researchers. Respondents completed the validated Multidimensional Health LOC scale. Mixed regression models were used to determine associations between interval locus of control scores and utilities, adjusting for demographic variables, HNC stage and type. **RESULTS:** Utility values were elicited from 101 respondents with a mean age of 47 years (48% male). Mean utilities were: 0.62 for locoregional laryngeal, 0.61 for locoregional non-laryngeal, 0.57 for recurrent non-laryngeal, 0.56 for recurrent laryngeal, 0.52 for metastatic non-laryngeal, 0.50 for metastatic laryngeal, and 0.34 for post-progression, HNC. There was suggestive evidence that LOC was associated with utilities ($P = 0.079$). Respondents who had a dominant *Chance* LOC rated health states significant lower ($P = 0.012$): for every one unit increase on the *Chance* subscale, there was a decrement of 0.011 in mean utility value. **CONCLUSIONS:** This evidence indicates that LOC is a determinant of utilities for head and neck cancer health states. Replicating these findings in other populations and diseases would shed insight into the psychosocial determinants of preferences.

PCN107

EVALUATION OF QUALITY OF LIFE FOR ANTI-CANCER TREATMENT AMONGST KOREAN METASTATIC BREAST CANCER PATIENTS: A MULTICENTER, CROSS-SECTIONAL STUDY

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OBJECTIVES: This research is designed to reveal Quality of life of Korean patients with metastatic breast cancer for cancer treatments. **METHODS:** This is a multicenter, cross-sectional study in breast cancer patients receiving palliative chemotherapy. Total 199 patients with metastatic breast cancer were interviewed from 4 centers. Clinical, socio-demographic, and quality of life data were collected. Subjects completed a face-to-face interview with trained interviewer to assess their health status for breast cancer treatment. Patients recalled the before diagnosis status under current situation. we used the three methods to evaluate the health status; EORTC QLQ-C30, BR-23, EQ-5D. **RESULTS:** Overall utility weights for EORTC QLQ C30 and EQ-5D was 0.81 and 0.78 respectively(before diagnosis). It is higher than those of current (EORTC QLQ-C30: 0.54, EQ-5D: 0.60). the patients who are before diagnosis estimated higher functioning score compared to current. (physical functioning scale; before cancer: 92.8, current 65.3) The higher the score is, the better patients' function is. Symptom scale scores are the similar with functioning scale scores. The higher the score is, the worse the symptom is. before cancer status has lower symptom scale scores than current. (fatigue symptom scale; Before cancer: 25.2, current: 48.5) BR 23 scale, there were deteriorations in patients for all domains compared to scores of before cancer patients. Especially, patient' current body image score is significantly lower than that of before diagnosis patients. (before diagnosis: 91.4, current: 46.4) **CONCLUSIONS:** There are few study of Quality of life in breast cancer patients. It is meaningful that this study provided the utility weights for breast cancer patients in Korea.

PCN108

PSYCHOMETRIC VALIDATION OF A PATIENT QUESTIONNAIRE EVALUATING SATISFACTION WITH A DARBEPOETIN ALPHA PRE-FILLED DEVICE FOR SELF-INJECTION (ARANESP®SURECLICK™DEVICE), AND A HOME-SERVICE (2CARE®SERVICE) IN CHEMOTHERAPY-INDUCED ANAEMIC CANCER PATIENTS

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OBJECTIVES: To validate a questionnaire evaluating patient satisfaction with the darbepoetin alpha pre-filled device for self-injection (Aranesp®SureClick™device) and the 2care®service for product delivery and helping patients with injection at home. **METHODS:** Patients with non-myeloid malignancies to be treated with 500mcg darbepoetin alfa three-weekly for chemotherapy-induced anaemia using the Aranesp®SureClick™device and 2care®service were enrolled in a prospective, observational study in the The Netherlands. Following each of the first three darbepoetin alpha-injections, patients completed a questionnaire specifically developed for this study. This questionnaire included items (answer ranges, 0–10) related to satisfaction with the device (5 items: ease-of-use/pain /anxiety/expectations/overall-satisfaction) and the 2care®service (9 items: quickness/delivery/punctuality/friendliness/competency/flexibility/information/usefulness/overall-satisfaction). Questionnaire structure was defined using factor analyses and confirmed by multi-trait analysis. Internal consistency was evaluated by Cronbach's alfa. Ranges of minimal important differences (MIDs) were calculated using anchor-based and distribution-based methods. Determinants of overall satisfaction with the Aranesp®SureClick™device were analyzed by multiple regression analyses. RESULTS: A total of 283 patients were evaluable. At first injection, median item-scores ranged from 8.0–9.4. Two composite scores were defined (1 item not correlated with any scores: quickness 2care®-contact making appointment): *satisfaction with the Aranesp®SureClick™device* and *satisfaction with the 2care®service*. Item-score correlations ranged from 0.61–0.81 and 0.64–0.79, respectively. Cronbach's alfas were 0.85 and 0.84. All items met convergent and discriminant validity criteria. Plausible MIDs were 0.5–0.7 and 0.3 for satisfaction with the Aranesp®SureClick™device and 2care®service, respectively. At first injection, satisfaction with the Aranesp®SureClick™device was mainly determined by expectations, pain, and ease-of-use. After 3 injections, the main driver was ease-of-use. **CONCLUSIONS:** Patients were satisfied with the Aranesp®SureClick™device and 2care®service. The satisfaction questionnaire showed good dimension structure and internal consistency reliability. MIDs were provided for interpretation of scores. Determinants of patient satisfaction were shown to change (ease-of-use becoming the main driver, while pain importance decreased) while the patient accumulates experience with the Aranesp®SureClick™device.

PCN109

DEVELOPMENT OF THE PATIENT-REPORTED VERSION OF THE COMMON TERMINOLOGY CRITERIA FOR ADVERSE EVENTS (PRO-CTCAE)

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OBJECTIVES: The standard lexicon for reporting adverse events in NCI-sponsored trials is the Common Terminology Criteria for Adverse Events (CTCAE), which consists of over 800 individual items. Currently, all items are reported by clinicians. However, multiple studies have found that clinicians tend to underreport symptom severity and onset compared with patient self-reports. In October 2008, the NCI contracted a multi-institution consortium to develop patient versions of CTCAE items, and an administration electronic platform. **METHODS:** A multidisciplinary committee systematically identified CTCAE items with sufficient subjective component to be amenable to patient reporting. Systematic reviews of publications and existing questionnaires, and analyses of existing data sets were conducted to determine optimal formats for questions and response options, and plain-language terms for each new "PRO-CTCAE" item. Cognitive interviews were conducted in 100 patients to refine items. **RESULTS:** Seventy-seven "symptoms" were identified in the CTCAE which were amenable to patient reporting. The committee determined that measured attributes for each symptom should include frequency, severity, and activity interference, assessed via discrete questions for each symptom. A standardized format for questions and response options, and plain language terms for each symptom were formulated. A web-based platform was developed for creating and administering the new PRO-CTCAE items. **CONCLUSIONS:** A patient version of the CTCAE system, known as the PRO-CTCAE, has been developed. This prototype is undergoing further testing to assess its validity, reliability, usability, and feasibility for use in a variety of cancer care settings. The PRO-CTCAE system both will enhance adverse event reporting by directly integrating patient experiences and will foster consistency of data collection methods across studies.

PCN110

HOW MUCH DO PATIENTS WITH RENAL CELL CARCINOMA (RCC) VALUE PROGRESSION FREE SURVIVAL IN MEDICAL DECISION MAKING?—RESULTS FROM A BENEFIT-RISK CONJOINT STUDY

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BACKGROUND: Overall survival (OS) has been traditionally used as the primary endpoint in oncology trials, however cross-over to 2nd line agents may result in biases for OS. Recent trials have used progression free survival (PFS) as the primary endpoint. Understanding patient preferences regarding expected PFS vs. avoidance of risk for toxicities in medical decision-making is needed. **OBJECTIVES:** To estimate RCC patients' willingness to accept toxicities and medication-related risks to increase PFS. **METHODS:** US residents aged 18 years and over with RCC completed a web-enabled, choice-format conjoint survey that presented a series of 12 trade-off questions, each including a pair of hypothetical RCC medication profiles. Each profile was defined by efficacy (PFS), tolerability effects (fatigue, diarrhea, hand-foot syndrome, mouth